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November 7, 2001

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

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Subject: Comments on HPV Test Plan and Robust Summaries for p-Methylstyrene

Dear Administrator Whitman:

The following comments on Deltech Corporation's test plan for p-methylstyrene are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than nine million Americans.

Deltech Corporation's test plan represents a clear violation of the October 1999 Agreement as well as the original HPV framework. Although Deltech Corporation provided robust summaries for all SIDS endpoints, it has proposed to repeat aquatic toxicity tests on fish without any justification. In addition, no information is presented about p-methylstyrene's physicochemical properties and applications. This type of basic information is useful in understanding a chemical's uses, behavior, and potential exposure scenarios. Finally, the test plan was posted in July 2001, nearly one year after the target date for completion of the experiments, which was listed as September 2000. Conducting experiments before subjecting the test plans to the public review process violates not only the October 1999 animal welfare guidance, but also the original HPV framework, which called for a 90-day comment period before commencing testing.

Our two main objections to the test plan address the violations of the following terms of the October 1999 Agreement for minimizing duplicative and/or irrelevant animal tests:

- 1. In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested.**

- 10. Companies shall allow 120 days between the posting of test plans and the implementation of any testing plans.**

- 1. In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested.**

Deltech Corporation submitted four acute fish toxicity studies, two of which were deemed acceptable. The company failed to provide any rationale for repeating these tests on animals.

Furthermore, p-methylstyrene is not expected to undergo hydrolysis or bioconcentrate in aquatic organisms, because it lacks hydrolyzable functional groups. Generally, benzenes and alkenes are resistant to hydrolysis. Therefore, any testing conducted will be completely irrelevant.

Given the extensive understanding of aquatic microorganisms and *in vitro* test methods, any further toxicity testing on fish is wholly inappropriate and unnecessary. *In vitro* tests with the protozoan *Tetrahymena* are frequently used as a measure of aquatic toxicity in ecological risk assessments (Larsen 1997). The biochemistry and physiology of *Tetrahymena* have been thoroughly investigated since the 1950s, and *Tetrahymena*, especially *T. pyriformis*, have been used for aquatic toxicity testing since the 1970s. Moreover, the genomics of the organism are currently being elucidated. The *T. pyriformis* population growth test is quick, easy, and cheap, and has incredible breadth (Schultz 1997).

The EPA has a massive database on the acute toxicity of more than 600 organic chemicals to fish called "Acute Toxicities of Organic Pollutants to Fathead Minnows (*Pimephales promelas*).". Comparisons of toxicity test results from the *in vitro* TETRATOX assay and the EPA's fish acute toxicity data have yielded good correlation between the two methods (Sinks 2001). Similarly, good correlation was observed between ciliate and guppy fish toxicity (Seward 2001). Evaluation of *in vitro* and *in vivo* aquatic toxicity data have allowed researchers like Schultz and colleagues to develop models to predict toxicity based on quantitative structure activity relationships, QSARs (Schultz 1999, Schultz and Cronin 1999, Niculescu 2000). Both the *in vitro* TETRATOX assay as well as QSARs provide more humane, efficient methods to predict aquatic toxicity at the screening level. We have an ongoing dialogue with the EPA about the incorporation of these alternative, nonanimal methods into the HPV program.

10. Companies shall allow 120 days between the posting of test plans and the implementation of any testing plans.

The EPA posted Deltech Corporation's submitted test plan for p-methylstyrene in July 2001, nearly one year after the target date for completion of the experiments. It has completely dismissed the importance of the public review process and stakeholder input, and violated not only the animal protection agreements, but also the original framework that the HPV participants agreed to follow, which called for a 90-day comment period between submitting proposed test plans and implementing them.

In conclusion, Deltech Corporation's test plan violates the October Agreement and the original HPV framework, by proposing to repeat acute toxicity tests on fish and daphnia without rationale and by bypassing the entire public review process. The EPA needs to ensure that participating companies adhere to the terms and spirit of the HPV program and the October 1999 Agreement.

Thank you for the opportunity to comment. I can be reached at 202-686-2210, ext. 302, or via e-mail at <ncardello@pcrm.org>. Correspondence should be sent to my attention at PCRM, 5100 Wisconsin Ave., N.W., Suite 400, Washington, DC 20016. I look forward to your response on these important issues.

Sincerely,

Nicole Cardello, M.H.S.
Staff Scientist

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